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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,761	11/13/2003	Barry E. Boyes	10030532-1	3579

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EXAMINER	
MOSS, KERI A	

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
11/12/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPOPS.LEGAL@agilent.com

Office Action Summary	Application No.	Applicant(s)	
	10/713,761	BOYES ET AL.	
	Examiner	Art Unit	
	KERI A. MOSS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Previous rejections under 35 USC 112, 2nd paragraph have been withdrawn in light of applicants' amendments and arguments.

2. Previous rejections under 35 USC 102 under Bailey have been maintained in light of applicant's amendments and arguments.

New Grounds for Rejection under Jindal have been made in light of applicant's amendments.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims **2-5 and 27** are rejected under 35 U.S.C. 102(a) as being anticipated by Bailey, Jerome et al (Removing High-Abundance Proteins from Serum, Genetic Engineering News, 1 November 2003, pp.32, 36-37, Vol. 23, No. 19). Bailey et al. teach a method of evaluating the specificity of a first stationary phase for at least one constituent present in a sample comprising sequentially contacting a sample with at least a first stationary phase (the Multiple Affinity Removal column, hereinafter "Bailey's column") and a second stationary phase (material based on Cibacron Blue) under chromatographic conditions, wherein the specificity of the first stationary phase for at

least one constituent present in the sample is uncertain (proteins in Table 1) and the specificity of the second stationary phase for the at least one constituent present in the sample (albumin) is certain (pgs. 36-37 Specific Removal of Targeted Proteins). The specificity is certain when it is known that the sample binds non-specifically or not at all. The sample is contacted with the first stationary phase then the second stationary phase (pgs. 36-37 Specific Removal of Targeted Proteins). The method further comprises contacting the sample with a first stationary phase to bind a fraction of the sample that comprises the at least one constituent; separating the binding fraction from the first stationary phase; and contacting the binding fraction with the second stationary phase (p.37, 2nd full paragraph). The first stationary phase comprises a pharmaceutical agent (polyclonal antibodies) and the method is a method of determining the specificity of the pharmaceutical agent for said at least one constituent present in the sample (pgs. 36-37).

5. Claims **2-5 and 27** are rejected under 35 U.S.C. 102(b) as being anticipated by Jindal et al. (US Pub 2002/0150926). Jindal et al. teach a method of evaluating the specificity of a first stationary phase for at least one constituent present in a sample comprising sequentially contacting a sample with at least a first stationary phase and a second stationary phase under chromatographic conditions (see [182]-[190], [206], [227], [242], [244]), wherein the specificity of the first stationary phase for at least one constituent present in the sample is uncertain (the column comprising antibodies) and the specificity of the second stationary phase for the at least one constituent present in

the sample is certain (the control column). The specificity is certain when it is known that the sample binds non-specifically or not at all. The sample may be contacted with the first stationary phase then the second stationary phase (see [182]-[190], [206], [227], [242], and [244]). The method further comprises contacting the sample with a first stationary phase to bind a fraction of the sample that comprises the at least one constituent; separating the binding fraction from the first stationary phase; and contacting the binding fraction the second stationary phase (see [182]-[190], [206], [227], [242], [244]). The first stationary phase may comprise a pharmaceutical agent and the method is a method of determining the specificity of the pharmaceutical agent for said at least one constituent present in the sample (see [182]-[190], [206], [227], [242], and [244]).

Response to Arguments

6. Applicant's arguments see Amendment, filed August 12, 2008, with respect to the rejections under 35 U.S.C. § 112, 2nd paragraph have been fully considered and are persuasive. The rejection of claims 2-5 and 27 under 35 USC § 112, 2nd paragraph has been withdrawn.

7. Applicant's arguments filed August 12, 2008 with respect to the rejections under 35 U.S.C. § 102 under Bailey have been fully considered but they are not persuasive.

8. First, Applicants argue that all of the antibodies in the column described by Bailey are of known specificity to serum proteins. The Examiner respectfully disagrees with Applicant's interpretation of the article. While the column was designed to remove the

targeted proteins (p. 32, 3rd column), there is no evidence in the article that Bailey et al. knew the specificity of Bailey's column for these targeted proteins. The specificity of these targeted proteins for Bailey's column was unknown prior to the method steps disclosed in the article. In other words, Bailey predicted that the proteins would bind to Bailey's column, but relied on the steps disclosed in the article to determine the specificity of Bailey's column for the targeted proteins. This is demonstrated by Bailey's use of the control column, the Cibacron Blue column, on p. 37. The Cibacron Blue column was used to assess how many proteins bind nonspecifically to the Cibacron Blue column but not to Bailey's column (p. 37 first column). Thus, the Cibacron Blue column was used as a control to evaluate the specificity of Bailey's column for the targeted proteins.

9. Second, Applicant argues that Bailey's use of the Cibacron Blue column is "for the purpose of demonstrating the greater specificity of Bailey's column over the Cibacron Blue column" (Amendment filed August 12, 2008, p.11). Similarly, the Examiner believes Bailey is evaluating each column's relative specificity for a constituent, which reads on "evaluating the specificity of [a] first stationary phase for [an] at least one constituent present in [the] sample" as claimed in claim 2.
The specificity is certain when it is known that the sample binds non-specifically or not at all.

10. Applicant's arguments with respect to claims 2-5 and 27 under Jindal have been considered but are moot in view of the new ground(s) of rejection. Applicant argues that Jindal fails to teach the claimed stationary phase with specificity for at least one

constituent present in the sample which is certain. In the Examples, Jindal teaches a stationary phase with uncertain specificity (a screening column) and a second stationary phase with certain specificity (a control column) for a constituent in the sample.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI A. MOSS whose telephone number is (571)272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Keri A. Moss/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797